

Remarks

Claims 30-36, 39-41, and 51-117 are pending in the application. Claims 39-41, 53-58, 61, 62, 74-79, 82, 83, 95-100, 103, 104, 116 and 117 have been withdrawn from consideration following a restriction requirement and a telephonic election without traverse by the applicant. That election is hereby confirmed. Claim 63 has been amended herein with the addition of the limitations of dependent claim 70. Claim 70 has been canceled.

Claims 63-69 and 80 have been rejected under 35 USC 103(a) as being unpatentable over Richter et al. (5755734) in view of Peale (15192). In response, the applicants have amended claim 63 by the addition of the limitations of dependent claim 70, which was not subject to this grounds for rejection. Therefore, it is now believed that claim 63 and dependent claims 64-69 are patentable over the Richter et al and Peale references and the rejection should be withdrawn. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 30-34, 59, 60, 63-70, 80, 81, 84-92, 101, 102 and 105-115 have been rejected under 35 USC 103(a) as being unpatentable over Quijano et al (5500014) in view of Richter et al '734. In response, the applicants respectfully traverse the rejection. Claims 30, 63, 84 and 108 are the independent claims rejected under this combination of references. The remarks relating to the independent claims are also believed to obviate the rejections of the dependent claims. Claim 30 relates to a vascular prosthetic device in which two valvular conduits are joined at a seam at an inflow end with a valve of fixed tissue housed within each of the valvular conduits. The seam joining each of the conduits are at the upstream end of the device and upstream of the valves. The inflow end of the device is larger in cross section than an outflow end. In the Quijano et al reference, a valvular conduit is disclosed which has fixed tissue valve residing within the conduit. The intended use of this device is to surgically replace a valve in various parts of the body, such as a venous valve or to reroute blood in the body where a valve is required to prevent backflow. However, there is no teaching that two such conduits could be joined

together in the manner set out in claim 30. In the Richter et al reference a bifurcated stent is disclosed which could be inserted into a blood vessel. The stent is formed from at least two sheets of material with each sheet being bent into the shape of one of the legs of the stent and a stem portion with the stem portions being joined to form the bifurcation. The intended purpose of this device is to be implanted within a body conduit to reinforce a collapsing, partially occluded, weakened or abnormally dilated section of a blood vessel. The applicants submit that no prima facie case of unpatentability has been stated for the combination of references in this rejection and, in particular, that (1) the dissimilar teachings of these references would not have been combined by a person skilled in the art and (2) even if the teachings are combined, they fail to make the applicants' invention. The essential premise of the Richter et al invention is that the device should provide a support for a vessel that creates a clear passageway fluid flow. There is no disclosure of an internal component within the device that can obstruct or restrict fluid flow. Richter et al also fails to indicate a direction of flow in the device because flow is irrelevant if there is no valve or other structure internal to the device that is dependent on the direction of flow. Not so with the applicants' invention as set forth in claim 30. The applicant's invention is specific as to direction and orientation of the components. The seam joining the two valvular conduits is on the upstream side and the valves are downstream from the seam. Because Richter et al has no teaching of where a valve should be with respect to a bifurcation and in what direction the valves should open (i.e. to permit flow from an inflow to an outflow), it fails to teach the limitations set forth in the applicants' claim 30. In the rejection, the rejection states: "Richter et al. teach to join two conduits together at adjacent inflow ends (Fig. 10) forming a vascular prosthetic ..." The applicants respectfully traverse this characterization of the Richter et al reference. A careful review of the Richter et al reference failed to find the word "inflow" or any other word indicating the expected direction of fluid flow within the stent. Richter et al employs the words "proximal" and "distal" to identify various portions of the device but never words that indicate a direction of expected flow. Thus, the rejection of claim 30 should be withdrawn. With respect to claim 63, two valvular conduits of chemically fixed biological tissue with a valve housed are joined at a seam at an angled slice adjacent the inflow ends and upstream of each of the valves to form a body having a single inflow end

and a pair of legs each having an outflow end. Again, the limitations of orientation of flow with the valves in claim 63 are not met in the combination of Quijano et al and Richter et al for the same reason as set forth above. Thus, the rejection of claim 63 should also be withdrawn. With respect to claim 84, a vascular prosthetic has an inflow conduit comprising a manifold formed from the sealed attachment of donor valved blood vessels, the manifold formed upstream of each of the biological valves so as not to interfere with the effective operation of the biological valves, the inflow conduit with a cross-sectional area larger than the cross-sectional area of either of the inflow ends of each of the donor blood vessels, and an outflow conduit positioned downstream of each of the biological valves. Again, the limitations of orientation of flow with the valves in claim 84 are not met in the combination of Quijano et al and Richter et al for the same reason as set forth above. Thus, the rejection of claim 84 should also be withdrawn. With respect to claim 108, a vascular prosthetic has at least two fixed tissue valvular conduits, each of the conduits having an inflow end and an outflow end and a valve of fixed tissue housed therein in which each of said conduits is joined adjacent the inflow ends and upstream of each of the valves to form a single inflow end with a cross-sectional area larger than the cross-sectional area of any of the inflow ends of the valvular conduits. Again, the limitations of orientation of flow with the valves in claim 108 are not met in the combination of Quijano et al and Richter et al for the same reason as set forth above. Thus, the rejection of claim 108 should also be withdrawn.

In addition to the failure of the combined references to teach the invention, the references would not be combined by a person skilled in the art in the manner indicated by the rejection. Quijano et al and Richter et al teach devices of entirely different purposes and construction that fail to contain any suggestion for combining them to make the applicants' invention. In the Quijano et al reference, a valvular conduit is disclosed which has fixed tissue valve residing within the conduit. The intended use of this device is to surgically replace a valve in various parts of the body, such as a venous valve or to reroute blood in the body where a valve is required to prevent backflow. There is no teaching of making the device in a bifurcated form. In the Richter et al reference a bifurcated stent is disclosed which could be inserted into a blood vessel. The stent is

formed from at least two sheets of material with each sheet being bent into the shape of one of the legs of the stent and a stem portion with the stem portions being joined to form the bifurcation. The intended purpose of this device is to be implanted within a body conduit to reinforce a collapsing, partially occluded, weakened or abnormally dilated section of a blood vessel. There is no indication in Richter et al that the stent should serve, in itself, as a conduit for liquids such as blood. In particular, there is no indication that the stent should be imperforate so as to convey liquids. To the contrary, at column 4, lines 11-15 the stent sheets are indicated to be patterned or etched with perforations.

What Richter et al teaches, therefore, is that such a device could be used within a bifurcated conduit for purposes of providing additional support. It does not teach the application of bifurcation to unbifurcated vessels or conduits. Additionally, the insertion of an obstructing element (like a valve) into the device of Richter et al would be contrary to the teachings of Richter et al since it could prevent the device of Richter et al from performing its intended purpose of opening flow through an obstructed vessel. For these reasons, the rejection of claims 30-34, 59, 60, 63-70, 80, 81, 84-92, 101, 102 and 105-115 as being unpatentable over Quijano et al in view of Richter et al should be withdrawn.

Claims 51, 52, 72, 73, 93 and 94 have been rejected under 35 USC 103(a) as being unpatentable over Quijano et al '014 in view of Richter et al '734 as applied to claim 30 above, and further in view of Ehrenfeld (5156619). In response, the applicants respectfully traverse the rejection. The applicants' remarks above with regard to the combination of Quijano et al and Richter et al are also pertinent to this rejection and for the same reasons the applicants submit that this rejection should also be withdrawn. Ehrenfeld fails to include teachings as to the direction of flow and valve positioning in a bifurcated device. In fact, Ehrenfeld fails to mention valves at all. The rejection indicates that Ehrenfeld is cited for teaching that stitching can be used to form a seam in a bifurcated replacement vessel. This may be true, but it does not teach that stitching can be profitably used to make a joint in the metal stent of Richter et al. In Richter et al, the chosen means for joining the metal sheets is screwing, crimping soldering and especially welding. There is no teaching or suggestion in Ehrenfeld that stitching can be a suitable alternative for any of the joining methods set forth in Richter. Neither screwing,

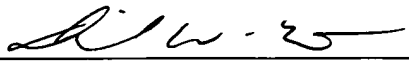
crimping, soldering crimping or welding is mentioned in Ehrenfeld as being alternatives for stitching. For these reasons, the rejection of claims 51, 52, 72, 73, 93 and 94 should be withdrawn.

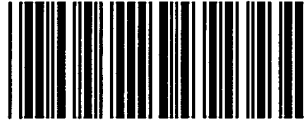
Claim 71 has been rejected under 35 USC 103(a) as being unpatentable over Quijano et al '014 in view of Richter et al '734 as applied to claim 63 above, and further in view of Mobin-Uddin (5078735). In response, the applicants respectfully traverse the rejection. The applicants' remarks above with regard to the combination of Quijano et al and Richter et al are also pertinent to this rejection and for the same reasons the applicants submit that this rejection should also be withdrawn. Mobin-Uddin fails to include teachings as to the direction of flow and valve positioning in a bifurcated device. In fact, Mobin-Uddin fails to mention that a valve could be profitably used in a device at all. The rejection indicates that Mobin-Uddin is cited for teaching that an angled slice of about 15 degrees can be used to form a seam in a replacement vessel. This may be true, but it does not teach that such a seam can be profitably used to make a bifurcation as in the joint in the metal stent of Richter et al. In Richter et al, the chosen means for joining the metal sheets includes cutting sheet material to provide portions which can be joined to form a stent bifurcation. There is no teaching or suggestion in Mobin-Uddin in of a bifurcation or a method of making a bifurcation. For these reasons, the rejection of claims 51, 52, 72, 73, 93 and 94 should be withdrawn.

For the reasons set forth above, claims 30-36, 51, 52, 59, 60, 63-73, 80, 81, 84-94, 101, 102 and 105-115 should be allowed. Reconsideration and allowance is respectfully requested.

Respectfully submitted,

Date 3/17/2003

By 
Daniel W. Latham, Reg. No. 30,401
Senior Patent Attorney
Tel. 763.391.9661
Fax. 763.391.9668



27581